VISI Barcode Subcommittee
Uniform Code Council, Inc.
April 27, 2000

Attendees:

Lori Easterday, Aventis
Ron Filipski, Aventis Pasteur
Jane Gilbert, Chiron Corp.
Katie Maher, Merck
James Mundt, Merck
Wikke Walop, Health Canada, Division of Immunization LCDC
Bruce G. Weniger, Centers for Disease Control and Prevention (CDC)

Donna Keller, PSC, Inc.
Andy Longacre, HHP/WelchAllyn
Rick Schuessler, Symbol Technologies
Ted Williams, Symbol Vision
George Wright, IV, Product Identification & Processing Systems

Jane Becker, UCC
James Chronowski, UCC
John Roberts, UCC
Frank Sharkey, UCC
Mary Wilson, UCC

The meeting convened at 9:40 AM.
The chair requested each participant to introduce himself or herself and provide a short description of their organization.

Bruce G. Weniger, MD, Assistant Chief for Vaccine Development, Vaccine Safety and Development Branch, National Immunization Program, Centers for Disease Control and Prevention (CDC), provided background of the problem for undertaking the "Vaccine Identification Standards Inititative" (VISI). One of the center's responsibilities is to track and assess the safety of vaccines administered in the USA, which requires accurate information in the medical record of the identity and lot number of the product administered, as mandated by law. The VISI is a cooperative effort of federal and state agencies, including FDA, vaccine manufacturers, professional medical and non-governmental organizations to develop voluntary guidelines for vaccine labeling and packaging, immunization recordkeeping, and medical communications. The principal VISI goal is to improve the accuracy and convenience of transferring vaccine identity and lot number from the vial into the patient's medical record, and onwards into immunization registries. Existing reports of vaccine adverse events indicate roughly 10% of medical records have missing or incorrect lot numbers or vaccine identities reported.

Immunization registries are organized at the local and state level to track which immunizations children have received, and permit parent reminder notices to be mailed and provide accurate histories of prior vaccinations when patients move to new health providers, a common occurrence.

Major components of the VISI application guideline are:

- Use of the 10-digit National Drug Code (NDC) to uniquely identify the vaccine administered. One problem is that the number is parsed in different ways, and has

led to unofficial insertions of zeros into the middle of the string by private databases, which leads to confusion in looking up vaccine identities. Another problem is that there is no up-to-date, user-friendly, accessible database that can be used by medical practice software developers to create the "lookup tables" to convert NDC numbers into recognizable vaccine brands and types. VISI has created a prototype database at www.cdc.gov/nip/visi/ndcsearch/ndcsearch.htm for this purpose. It permits searching with either formal 10-digit or unofficial 11-digit NDC numbers.

- Establishment of uniform guidelines for the display of key information in a "Vaccine Facts" sidebar modeled after FDA's mandated "Nutrition Facts" labeling on foods.
- Recommendation of one or more peel off identification labels on vaccine vials for use by clinics which did not have barcode scanning equipment and associated medical records software. A uniform vaccination administration record (UVAR) form is proposed for the patient's medical record to receive such stickers. Additional duplicate or triplicate stickers for each dose would make possible their use on patient take-home vaccination record "passports", as well as for forms to be mailed or faxed to immunization registries.
- Recommend barcoding of NDC, lot number, and expiration date on all vaccine outer ("secondary") packaging, vials ("primary" packaging), and peel-off stickers for those pharmacies, medical clinics, and immunization registries that have or will obtain the requisite scanning equipment. Manufacturing processes would likely require "online" printing of the lot number and expiration date barcodes. The barcoding could be done in several ways. For the outer packaging, there might be one or more standard linear one-dimensional barcodes containing all the data, for backward compatibility with laser wand scanner equipment. Or the lot number and expiry date could be in a 2-dimensional format which requires more sophisticated scanners. For the much smaller vaccine vial, space restrictions will likely require all data to be in a reduced-space symbology, permitting only the NDC to appear one-dimensionally. Because nurses often discard the outer cardboard packaging when storing multi-dose vials in the refrigerator between patients, it is essential that all key information be found on the vial.
- There is some desire to ensure compatibility of outer packaging barcodes with laser wand scanners capable of reading only one-dimensional symbols. But whether or not there will be sufficient demand by medical clinics to justify such backward compatibility with existing hardware is unknown.
- Standardization of abbreviations for vaccine manufacturers and vaccine types. The use of diverse abbreviations in written records hampers determination of which vaccine was actually received. This problem will be exacerbated as many new vaccines enter the market, especially combination products with longer and longer generic names. Upon FDA acceptance, the use of standard vaccine type abbreviations -- instead of full generic names -- could ease the difficulty of labeling the small vaccine vials and peel-off stickers.

Dr. Weniger asked the committee to help VISI determine what would be the best symbology(ies) and what the alternative options were, to specify for bar-coding the vaccine boxes, vials, and stickers.

The chair advised everyone to read the antitrust statement that was included in the packet of information before continuing. John Roberts reinforced the antitrust statement with further comments.

John Roberts gave an overview of the UCC.
Key points

- UCC is being utilized by the VISI for its expertise in product and process identification. Implementing these methods will reduce drug-related errors.
- The data encoded in the primary symbol is a license plate number associated with a product. The detailed information is in an associated database that the bar coded data identifies.
- The UCC is not a government agency. It is a not-for-profit organization in North American, with approximately 200,000 plus members.
- UCC is partnered with EAN International.in 93plus countries, another 600,000 plus members.
- 44 Countries have adopted UCC•EAN for identifying and bar-coding medical products.
- The CDC needs to examine standard XML technology for use in electronic vaccine purchase orders.

Ted Williams of Symbol Vision provided a technical overview of the RSS technology.

- The UCC/EAN System is based on data structures and data carriers.
- Key part of data structures is Global Trade Item Number GTIN.
- GTIN is the primary information but can be accompanied by secondary information to include expiration and lot number.
- UCC/EAN-128 can encode up to 48 characters in a single long symbol.
- Two levels of identification is needed in the pharmacy environment, expiration date and lot number. In the hospital environment, the NDC number is used to identify the correct vaccine before administering to the patient.
- The 14 data digit capacity RSS limited was developed for small items such as vials.
- RSS expanded to encode the GTIN on variable weight item.
- Composite Component – encode the supplementary data on small items.
    - 2D composite does not stand-alone.
    - Can be read with linear scanner.
    - CC-A Format will encode up to 56 characters
    - CC-B Format will encode up to 338 characters
    - CC-C Format will encode up to 2361 characters

The meeting was opened to discussion: The following are the result of this discussion:

- Scanners programmed to scan the RSS symbology will read any of the formats, automatically, without the need to make any adjustments.
- The primary (NDC) and secondary information may be printed on a container as two separate linear symbols. There are no alignment requirements between these two symbols. No linkage flag is required when employing this method.
- The linear carrier can be the UCC·EAN symbols that are scanned on a container of medicine today. Unless there is a reason to keep the UPC symbol, they should not be used. This application indicates the use of the RSS symbol and not a retail symbol on these products.
- Two symbols can be printed on the outer container, the primary symbol containing the NDC and the secondary symbol containing the lot id and expiration date.
- There is no way to verify printed symbols or other data on multi-layered labels.

- The recommended "x" dimension for printing the RSS symbol is the largest x dimension capable of producing a symbol to fit the label window size not to be less than 6.7 mils (0.0067inch).
- There is no empirical data available on the read rate vs. x dimension for the RSS family of symbols.
- Current Specifications: Use UCC·EAN 128 for primary information unless the product needs to be read at point of sale on outer package that use only one bar code symbol containing the medical industry requirements.

- Two objectives,
  - Inventory control
  - Vaccine tracking in administration

  Requirements:
  - UPC – Point of Sale compatibility
  - Lot number and Expiration Date

  One solution is to use the UPC/Composite. Primary identification in the UPC-symbol, lot number and expiration date in the composite component.

- The composite component is not printable with current ink-jet technology.
- Use two separate bar codes for the outer container. Preprint the UPC and post print a separate RSS/Composite symbol in another place on the outer container.
- Two systems are needed. One to print and one to verify what was printed.
- Minimum information for peel off label should include NDC, Human Readable, Pick number and/or lot number, Expiration Date (optional), Vaccine name in abbreviated form and abbreviation form of the manufacturer.
- Adventis is already producing the peel off labels without the UPC symbol.
- An alternate solution to peel off labels is to provide inexpensive point of use production of bar coded labels for application to forms.
- No guidelines are needed for placement of symbols on the outer container
- Approved minutes will be forwarded to the EAN with intention to begin implementation of global healthcare product identification specifications and guidelines.
- UCC will identify and contact high-speed printer suppliers (Norwood, Dako and others) and report back to VISI.

ACTION ITEMS:

- VISI members need means to identify vaccine information and download the information. VISI will contact all companies that have vaccines to meet and discuss the issues and set the guidelines.

- CDC will draft VISI guidelines. Possibly put it on a web page.
  Leave space on outer container for online printing the expiration date and lot number.
  Leave it up to the manufacturer's discretion for placement.
  Include vaccine ingredients on the sidebar.
- CDC will circulate the trace component issue and get a reaction.
- Sub-committee on technology was formed.

- All attendees to this meeting will be copied on this committee's findings. Notify committee if not interested.
- Ron Filipski and Katie Maher volunteered to be part of the technology subcommittee.

Mr. Wright motioned to adjourn and Mr. Roberts seconded the motion.

Meeting was adjourned at 3:00 p.m.